

EXAMINER'S AMENDMENT

1. The amendment after final rejection, filed 1 December 2009, has been entered. Claims 2, 4, 6-22 are pending.

2. The restriction between groups 2 (claims 2-10) and 3 (claims 11-14) as set forth in the office action mailed 2 June 2008 is vacated. Claims 11-14 are rejoined.

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ryan Brady on 28 December 28, 2009.

The application has been amended as follows:

4. In the specification:

At p. 1 line 1 the title has been replaced with:

-- Method of isolating cytotoxic heterocomplex associated with multiple sclerosis - - -

5. In the claims:

In claim 2, lines 4-6 have been deleted and replaced with:

isolating a heterocomplex from the biological sample, wherein the heterocomplex is chosen from a GM2AP/GM2/MRP14 heterocomplex and a mutated GM2AP/GM2/MRP14 heterocomplex in which mutated GM2AP has the amino acid sequence set forth in SEQ ID NO:2;

In claim 7, line 2, delete "the other said antibody" and replace with - - one of said antibodies - - -

Claim 8 has been re-written as follows:

The method of claim 2, wherein the biological sample is subjected to the following treatments prior to the step of isolating:

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digesting the proteins of the sample with proteinase K,
inactivating the proteinase K, and
neutralizing the pH.

Claim 11 has been re-written as follows:

A composition for detecting and/or quantifying a cytotoxic factor associated with multiple sclerosis comprising at least one antibody that specifically binds to a heterocomplex selected from the group consisting of:

- a GM2AP/GM2/MRP14 heterocomplex and
- a mutated GM2AP/GM2/MRP14 heterocomplex in which mutated GM2AP has the amino acid sequence set forth in SEQ ID NO:2.

Cancel claims 13-15

Claim 16 has been re-written as follows:

A method for detecting and/or quantifying a cytotoxic factor having a gliotoxic activity and associated with multiple sclerosis, comprising:

- providing a biological sample,
- digesting the proteins of the sample with proteinase K,
- inactivating the proteinase K,
- neutralizing the pH, and
- isolating a heterocomplex from the biological sample, wherein the heterocomplex is chosen from a GM2AP/GM2/MRP14 heterocomplex and a mutated GM2AP/GM2/MRP14 heterocomplex in which mutated GM2AP has the amino acid sequence set forth in SEQ ID NO:2.

In claim 20, line 1, delete "claim 18" and replace with -- claim 16 --

In claim 21, line 2, delete "the other" and replace with -- one --

6. The following is an examiner's statement of reasons for allowance: the translation of foreign priority document 0315265 is sufficient to antedate the reference by Perron 2004, cited

in the rejection under 35 USC 103(a) of the office action mailed 1 June 2009. Consistent with 37 CFR 1.55(a)(4)(ii) and MPEP § 201.15, applicant's representative has provided a statement that the translation is accurate (see remarks filed 1 December 2009, p. 7 section IV). Therefore the rejection under 35 USC 103(a) is overcome. The prior art does not teach or suggest the heterocomplex recited in independent claims 2 and 11.

The rejection under 35 USC 102(b) is overcome as applicant has incorporated the subject matter of dependent claim 3 not subject to the rejection for anticipation into claim 2. Claim 2 requires that an antibody that binds specifically to the heterocomplex be used; such antibodies are defined at p. 9 of the specification as excluding antibodies that bind to the individual proteins when they are not in the complex. Claim 6 narrows parent claim 4; although claim 6 discusses antibodies which bind to certain specific proteins within the heterocomplex, given the definition of antibodies that bind to the heterocomplex claim 6 is necessarily limited to methods of using antibodies that bind to these proteins only when they are part of the heterocomplex.

Newly-presented independent claim 16 requires the steps recited in claim 8, which the examiner had previously indicated as novel and non-obvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Daniel E. Kolker/

Primary Examiner, Art Unit 1649

January 6, 2010